

Thesis Approval Form

PATIENT PERCEPTION OF DISCLOSURE PERFORMANCE OF INFORMED
CONSENT ELEMENTS IN THE PREANESTHESIA INTERVIEW

Bradley Jay Hartgerink

APPROVED:

Patricia McMullen, CRNP, MS, JD, Chair of Committee Date

John P. McDonough, CRNA, EdD, Committee Member Date

Kenneth P. Miller, PhD, RN, FAAN, Committee Member Date

APPROVED:

Faye G. Abdellah, EdD, ScD, RN, FAAN Date
Dean

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ABSTRACT

Adequate disclosure during the informed consent process ensures equalization of the practitioner/patient relationship and patient decision-making rights. The purpose of this study was to provide a descriptive analysis of the extent to which patients report that the elements of informed consent (nature of the proposed anesthesia, benefits of the proposed anesthesia, material risks of the proposed anesthesia, and alternative anesthetic modalities) were discussed in the preanesthesia interview. A survey composed of 21 questions pertaining to demography and informed consent elements was devised and administered to 53 patients immediately following their preanesthesia interview. The nature, benefits, and risks of the proposed anesthetic were discussed more than average or in detail more than 90%, 81%, and 90% respectively. However, alternative anesthetic modalities were not or only somewhat discussed 30% of the time. This study found that during the preanesthesia interview, the type, benefits, and risks of the anesthetic were well discussed with the patient, but that patients do not perceive that anesthetic choices were being offered. A low statistical inverse correlation of -0.217 was found between the total score for the informed consent elements and the highest educational level attained. This suggests that the higher the patient educational level, the more inadequate was the perceived level of anesthetic disclosure by the anesthesia provider. A low statistical correlation of 0.370 was found between those identified by the patient as the provider and the actual provider. This indicates that patients are not clear on whether their provider is a nurse anesthetist or an anesthesiologist.

Key Words: Informed Consent (Research), Anesthesia, Perception, Survey Questionnaire, Patient Controlled Anesthesia, Patient Perception, Disclosure Performance, Preanesthesia Interview

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by

Bradley Jay Hartgerink

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DEDICATION

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CHAPTER 1: INTRODUCTION

Historical Overview

Informed consent is a relatively recent principle. The principle requires a physician to inform a patient of medical procedures and associated consequences so that the patient can then make an informed decision whether or not to submit to the treatment (Tomes, 1993). Before 1960, doctors were primarily concerned with their patients' awareness of the procedures to be performed. Whether to treat or not to treat was widely accepted to be the physician's decision (Mills, 1974).

In 1960, the Supreme Court of Kansas, in Natanson v. Kline (1960), held that a physician must disclose those consequences of treatment which a reasonable medical practitioner would disclose under the same or similar circumstances. This is also called the medical standard of informed consent. The movement toward greater patient disclosure did not stop there. The US Court of Appeals for the DC Circuit decided the landmark case of Canterbury v. Spence (1972), which established an even greater obligation on the part of the physician to disclose what an average, reasonable patient would consider material to his decision whether to accept the proposed treatment, also called the lay standard of informed consent.

Need for the Study

Currently, there is little research in the military or civilian sector to determine the extent of informed consent disclosure (presence of informed consent elements) in the

preanesthesia interview. An assessment of informed consent disclosure is valuable in determining areas where providers could give better information in order to improve quality of care and diminish legal liability. Follow-up studies on improved informed consent disclosure and improvement of anesthesia provider education with respect to informed consent are warranted.

Legal Theories

Self-determination. Informed consent is based on two legal theories. The first is the patient's right to self-determination, in which "every human being of adult years and sound mind has a right to determine what shall be done with his own body," Schloendorff v. Society of New York Hospital (1914). Self-determination was legitimized by Canterbury v. Spence (1972). In some states this legal theory has changed the standard to reasonableness (lay standard) from the standard of practice (medical standard) as decided by Natanson v. Kline (1960) (Mills, 1974; Roach, 1994). This change in philosophy places a much greater duty of disclosure upon practitioners and enables a patient/plaintiff to establish an informed consent case without having to produce expert medical testimony (Rosoff, 1979).

Fiduciary duty. The second legal theory that serves as a basis for informed consent is the fiduciary relationship between the patient and physician. A fiduciary duty is one owed by a party who is handling the affairs of another person (Rowland & Rowland, 1994). Whereas the practitioner has superior knowledge and/or bargaining power compared with the patient, the provider has the duty to give a fair and complete

disclosure of the informed consent elements. Practitioners should provide adequate information on the nature of the procedure, material risks, benefits of the proposed treatment, and alternative treatment modalities so that patients can weigh these factors against the benefits to be derived and can make a reasoned and intelligent decision about their course of treatment. Again, this second legal theory supports a thorough disclosure on the part of the practitioner.

The Problem Statement

Defining the scope of the problem. One of the perceptions of Certified Registered Nurse Anesthetists (CRNA) by the public and peers alike is the manner in which they provide quality of care to their patients (Jordan, 1994). Quality of care refers to activities involving patient/provider interactions that are solidly based on defined standards of practice. Providing this quality of care requires a patient advocate who ensures the patient is knowledgeable about anesthetic choices.

Twenty-five thousand nurse anesthetists administer more than 65% of the 26 million anesthetics given to patients in the US each year. They are at greater risk for medical malpractice litigation if they are not well versed in the principle of informed consent (Jordan, 1994). Even though no damages have been awarded to a plaintiff in the absence of accompanying injury, advances in medical technology and heightened consumer awareness among patients are fueling a rise in some kinds of informed consent claims (Gild, 1989). Contemporary judges and juries are often sympathetic to informed consent claims (Tomes, 1993). More important, in the age of consumerism, the principle

of informed consent attempts to ensure that the patient, absent certain emergency circumstances, will be the ultimate decision maker in his or her care (McMullen & Philipsen, 1993). “With proper informed consent, misinformation, dissatisfaction, and subsequent legal action can be diminished” (McDonough, McMullen, & Philipsen, 1995, p. 64).

Elements of informed consent. In order to satisfy the legal requisites of informed consent, the anesthesia provider must disclose the (1) nature of the proposed anesthesia; (2) benefits of the proposed anesthesia; (3) material risks of the proposed anesthesia; (4) alternative anesthetic modalities; and (5) outcome, if no treatment is performed (McMullen & Philipsen, 1996). In anesthesia practice the element that refers to outcomes, if treatment is not performed, is an inappropriate consideration in most surgical cases. Therefore, when referring to anesthesia, the first four elements of informed consent will be cited. Otherwise, five elements of informed consent will be cited when reference is made to medical practice in general.

If any of these informed consent elements are missing in the preanesthesia interview, the anesthesia provider could potentially be found liable for negligence if any harm is sustained by the patient (Gild, 1989). Consequently, the information which the anesthesia provider elicits during the preanesthesia interview is critical in influencing requisite disclosure and quality anesthetic care (LeBeuf v. Atkins, 1979).

Informed Consent in Military Settings. Anesthesia providers in the military are at risk as a result of inadequately informed consent disclosure during the preanesthesia interview. Active duty personnel have limited legal remedies against a military anesthesia

provider as a consequence of sovereign immunity. The Anglo-Saxon legal doctrine of sovereign immunity held that the Crown was immune from any suit to which it had not consented. Ultimately, this legal principle was invoked on behalf of the Republic and applied by our courts as vigorously as it had been on behalf of the Crown (Feres v. United States, 1950). Thus, wrongs that would have been actionable if inflicted by an individual or corporation remained remediless when the perpetrator was an officer or employee of the Government.

In Feres v. United States (1950), “The Supreme Court . . . held that the government was not liable under the Federal Tort Claims Act for injuries to servicemen arising out of or in the course of activity incident to military service” (p. 153). The significance of this decision under the Federal Tort Claims Act is that a member of military service who sustains injury due to the negligence of others in the armed forces cannot seek remedy from the Federal Government. “The purpose of the Tort Claims Act was to extend a remedy to those who had been without a remedy, rather than to make additional provision for those already provided for” (p. 153). Under sovereign immunity the government was held harmless for acts committed by federal employees. This immunity was rescinded in part by the Federal Tort Claims Act, which allowed certain parties to sue the government for tortious conduct by government employees. However, as decided in the case of Feres v. United States, the government retained its’ sovereign immunity as to active duty military personnel. Conversely, this case held that the Federal Tort Claims Act did allow suits against the government that were initiated by dependents and retirees. Even though the Feres Doctrine protects the Federal

Government from litigation from active duty personnel, dependents and retirees still have the right to bring legal action against the federal government.

Purpose of the Study

The purpose of this study was to describe the extent to which patients reported that the elements of informed consent were disclosed in the preanesthesia interview. Secondary aims of this study included the extent to which patients could identify the provider of preoperative anesthesia information and the relationship between certain demographic characteristics (age, marital status, military status, education) and the patients' reports as to the level of disclosure.

Research Questions

In an attempt to address some of the issues related to informed consent, this study seeks to answer the following questions:

1. What is the patient's report of the overall level of disclosure during the preanesthesia interview of each of the elements of informed consent?
2. Is there a relationship among a patient's gender, age, ethnicity, military status (active duty, dependent, etc.), marital status, educational status, time spent in the interview, level of comprehension, and the disclosure of the informed consent elements in the preanesthesia interview?
3. Do patients report a difference in the disclosure of the informed consent elements depending on whether an anesthesiologist or nurse anesthetist performed the preanesthesia interview?

Disclosure of each of the informed consent elements in the preanesthesia interview is the dependent variable studied. The independent variables are gender, age, ethnicity, military status, marital status, educational status, type of provider, length of interview, and level of comprehension.

Definition of Terms

Informed consent. A legal concept predicated on the duty of the practitioner to disclose to the patient information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it (Pozgar & Pozgar, 1996).

Adequate informed consent. Informed consent that addresses what an average, reasonable patient would consider material to his or her decision whether to accept the proposed treatment (McMullen & Philipsen, 1996).

Inadequate informed consent. Failure to obtain proper consent and/or information regarding the proposed treatment that an average, reasonable patient would consider material to his or her decision.

Certified Registered Nurse Anesthetist (CRNA). A registered nurse who is educationally prepared and competent to engage in the practice of nurse anesthesiology. All CRNAs are responsible and accountable for individual professional practice and are capable of exercising independent judgment within their scope of competence and licensure. They accept the responsibility for rendering professional services and the evaluation of the effects of those services on the patient. The practice of CRNAs is a recognized specialty within the

profession of nursing and is not a medically delegated act. CRNAs are recognized in all 50 states by designated state licensing or regulatory bodies, primarily boards of nursing (Jordan, 1994, p.4).

Anesthesiologist (MDA).

I. Definition of Anesthesiology: Anesthesiology is a discipline within the practice of medicine specializing in:

- A. The medical management of patients who are rendered unconscious and/or insensible to pain and emotional stress during surgical, obstetrical, and certain other medical procedures (involves preoperative, intraoperative and postoperative evaluation, and treatment of these patients);
- B. The protection of life functions and vital organs (e.g., brain, heart, lungs, kidneys, liver) under the stress of anesthetic, surgical, and other medical procedures;
- C. The management of problems in pain relief;
- D. The management of cardiopulmonary resuscitation;
- E. The management of problems in pulmonary care; and
- F. The management of critically ill patients in special care units.

II. Anesthesiologist's Responsibilities: Anesthesiologists are physicians who, after college, have graduated from an accredited medical school and have successfully completed an approved residency in anesthesiology and, in addition, may have had additional training in critical care medicine and pain management.

Anesthesiologists' responsibilities to patients include:

- A. Preanesthetic evaluation and treatment,
- B. Medical management of patients and their anesthetic procedures,
- C. Postanesthetic evaluation and treatment, and
- D. On-site medical direction of any nonphysician who assists in the technical aspects of anesthesia care to the patient (American Society of Anesthesiologists, 1997, p. 406).

CHAPTER 2: REVIEW OF RELEVANT LITERATURE

Two major areas of the law, tort law and contract law, are relevant when a patient does not receive adequate informed consent. This chapter will discuss tort and contract law principles, as well as *Res ipsa loquitur*, and their relevance to informed consent in the preanesthesia interview.

Tort Law

A tort is a wrongful act committed by one person against another person or property (Aiken & Catalano, 1994). Torts are private civil wrongs as opposed to crimes which are public wrongs. When a plaintiff files a lawsuit, a tort claim is submitted to recover damages for personal injury or property damage occurring from negligent conduct or unintentional misconduct (Prosser, 1984). The purpose of tort law is to make the injured party whole again through monetary compensation (Aiken & Catalano, 1994).

There are two types of torts. The first type, unintentional tort, occurs when a person suffers harm or injury as a consequence of an unintended, wrongful act by another person (Aiken & Catalano, 1994). Negligence, malpractice, breach of confidentiality, and lack of informed consent are examples of unintentional torts. The second type, intentional tort, involves the planned and conscious touching of the patient (Peters, Fineberg, Kroll, & Collins, 1983). Intentional torts include assault, battery, and false imprisonment. This thesis will deal with unintentional torts.

Negligence. In the 1950s, courts realized that the actions alleging inadequate informed consent differed from those arising from a total lack of consent (Tomes, 1993).

Inadequate informed consent is based on negligence, which is failure to use due care. Whenever a practitioner withholds (consciously, inadvertently, or deceptively) any facts necessary to form the basis of an intelligent consent by the patient to the proposed treatment, the practitioner violates his or her duty to the patient. Therefore, the practitioner has the responsibility to provide the proper information to enable the patient to make an informed choice regarding alternative procedures and associated risks. The modern principle of informed consent rests on negligence theory. In informed consent cases based on negligence, the plaintiff must prove that the defendant breached a duty to disclose information and prove that the failure to adequately disclose that information harmed the patient. The harm exists when disclosure of the material risks inherent to a particular treatment would have resulted in the patient deciding against the treatment or would have elected an alternative treatment.

Negligence occurs when a person fails to act in a reasonable manner under a given set of circumstances (Prosser, 1984). Malpractice is negligence committed by a professional. This relates to informed consent when there is failure to disclose what a reasonable, prudent provider would under the same or similar circumstances (e.g., fails to meet the standard of care). In lawsuits involving informed consent under negligence theory, the issue is whether or not the amount disclosed is below the standard (lay or medical standard, depending on the state) established by law for the protection of others (McMullen & Philipsen, 1996). Through established legal precedence the courts have placed the responsibility on the injured patient to establish that the provider's disclosure fell below the standard of care (McMullen & Philipsen, 1996).

In order to prove that the provider's disclosure fell below the standard of care, Aiken & Catalano (1994) assert that the plaintiff must provide evidence concerning the following: "(1) a duty owed to the plaintiff, (2) a breach of duty or standard of care by the professional, (3) a proximate cause or causal connection between the breach and the harm or damages, and (4) actual harm or damages suffered by the plaintiff" (p. 9).

A duty is defined as a legal obligation toward the patient (Aiken & Catalano, 1994). In anesthesia cases, the legal obligation is typically established via a written contract between the institution (hospital, anesthesia group, military, etc.) and the patient. The patient agrees to pay a fee in exchange for not only reasonable anesthesia administration by the provider, but also a thorough disclosure of the four elements of informed consent (Lord, 1990). Even if the contract is unwritten, courts will imply the duty element and services must be reasonable. Although most malpractice suits could be pursued as a breach of contract action, most plaintiffs file a tort action for negligence because monetary damages are traditionally more substantial (Prosser, 1984).

The second element of negligence as it applies to informed consent considers whether the provider's disclosure violated his duty to the patient (McMullen & Philipsen, 1996). In order to determine whether or not there was a breach of duty, the plaintiff must prove that the provider's disclosure did not comply with reasonable standards of care (Prosser, 1984). Professional journals, texts, standards developed by professional organizations, and institutional protocols can be used to determine whether or not the provider's care complied with reasonable care (McMullen & Philipsen, 1996; Prosser, 1984). Also, any written documentation, such as the preanesthesia form

documenting the content discussed during the interview, subsequent preanesthesia progress notes, and the written informed consent document itself can be used to assist in determining whether adequate disclosure was given.

The third element, causation, addresses two issues in informed consent cases: (1) whether the provider's nondisclosure caused the patient to make an uninformed decision that led to an injury, and (2) whether the patient's injury was foreseeable (Aiken & Catalano, 1994; Prosser, 1984). Foreseeability becomes an issue when material risks are purposely or inadvertently not disclosed to the patient, and the patient subsequently sustains an injury related to one of the nondisclosed material risks (Aiken & Catalano, 1994).

The fourth element, damage, necessitates that the patient sustain an injury in order to recover from a provider (Prosser, 1984). For example, if the anesthesia provider neglected to inform a patient that a seizure could result from a local anesthetic administered intravascularly during an epidural procedure and the patient does not sustain a seizure, then the damage element would be missing, thereby making a malpractice suit unsuccessful.

If sufficient evidence establishes that all of the elements of negligence or malpractice are present, the plaintiff is entitled to actual damages and damages for pain and suffering (Danzon, 1985). In cases where the patient's conduct contributes to the injury, some states either reduce the amount of damages or deny damages altogether (Prosser, 1984).

Assault and Battery. The second type of tort, an intentional tort, imposed for failure to obtain the consent of the patient is an assault and battery action (Peters et al., 1983). An assault is defined as a deliberate act wherein one person threatens to harm another person without his or her consent and has the ability to carry out the threat (Prosser, 1984). In order to be held liable for assault and battery, a defendant must have committed a direct act intended (planned and conscious) to cause an unpermitted contact (Peters et al., 1983). It is the absence of consent to the contact on the part of the plaintiff, not the hostile intent of the defendant, which is the essence of an action for assault and battery. Thus, a plaintiff's cause of action for an assault and battery must fulfill three criteria alleging: (1) the defendant's intentional act that resulted in, (2) the offensive contact with the plaintiff, and (3) the plaintiff's lack of consent thereto.

The primary issue considered in assault and battery cases is what constitutes adequate consent. For the anesthesia provider a specific written consent to anesthesia is the most desirable. However, the written consent is only an *indicia* that the provider made an adequate disclosure. For example, if the patient only speaks Spanish and the provider has the patient sign the written consent knowing the patient did not understand, the written consent is not valid. In addition to written consent, oral consent to anesthesia has also been deemed valid (Peters et al., 1983).

There are some exceptions to the rule. In emergency situations, when the patient is unable to consent, the anesthesia provider can assume implied consent and administer anesthesia. Another exception to informed consent is therapeutic privilege (McMullen & Philipsen, 1996). In this case the courts recognize that in some instances a complete

disclosure might constitute a therapeutic detriment to the patient (Peters et al., 1983). For example, in Hall v. United States (1955), the court held that therapeutic privilege might apply to disclosure of anesthesia risks to the obstetrical patient in the delivery room. Many of these patients are anxious, and it might be deleterious to disclose the risks of regional anesthesia (i.e., death, paralysis, and seizures) to this particular group of patients. Because the use of therapeutic privilege involves medical judgment, expert testimony is usually required to prove it has been properly exercised. Thus, the burden of proof in exercising therapeutic privilege is the provider's (Peters et al., 1983). Peters and colleagues (1983) also note other exceptions to the provider's duty to disclose. These include cases where:

- (1) The patient is already aware of risk,
- (2) The existence of the risk is a matter of common knowledge (the patient's knowledge of that risk may be inferred),
- (3) The risk was not generally known to the medical community at the time that procedure was carried out,
- (4) The risk exists only when the procedure is negligently or improperly performed, and
- (5) The patient expressly requests that he or she not be informed. (p. 24)

Contrasting Battery and Negligence in Tort Law. As noted previously consent cases can arise in one of two ways under tort law: (1) battery for the performance of procedures different from or in excess of those to which the patient consented, or (2) negligence for the performance of procedures to which the patient consented, but fails to

disclose certain risks and results involved in the procedure and thereby fails to obtain informed consent (Tomes, 1993). The major distinction between battery and negligence with regard to informed consent is that in battery there is no consent given for the procedure; in negligence, inadequate informed consent is given to the patient by the provider.

In the 1950s, the law began to recognize that patients have the right to consent to medical procedures. Judicial decisions establishing this principle arose from physicians' failure to get permission from their patients to perform surgery (Tomes, 1993). The courts recognized the patients' right to be free from an unauthorized touching by allowing them to sue as a victim of battery, entitling them to damages. Under battery the plaintiff need not prove that the provider is negligent. Rather, the plaintiff must prove that the provider touched the plaintiff without the patient's consent. Therefore, a patient can have a successful surgery and his post-surgical status can be much improved over his pre-surgical status; but, if the surgeon exceeded the scope of the proposed surgery or the surgery was different from the one consented to, then the provider may be found liable for battery (McDonough et al., 1995). Even though monetary damages are not as substantial from a plaintiff's perspective, bringing a battery case against a practitioner may be more advantageous than bringing a negligence case. The plaintiff merely has to prove that unconsented touching occurred, not that inadequate informed consent was given on behalf of the practitioner (Tomes, 1993).

In the case of Bang v. Charles T. Miller Hospital (1958), the Supreme Court of Minnesota reversed an earlier decision by a district court on appeal. The court found that

the evidence presented a question for the jury as to whether or not there was an assault or an unauthorized operation on a patient due to a failure to obtain his consent. The plaintiff contended that the severance of his spermatic cords in connection with a prostate operation was not authorized. The physician never presented the patient with the option of either severing the spermatic cords, resulting in sterility and preventing a possible postoperative infection, or not severing the spermatic cords, thereby maintaining the patient's fertility with the possibility of contracting a postoperative infection. The court found that (1) informed consent must be properly obtained from the patient or a legal surrogate in those cases where the patient is not legally competent; (2) in an emergency situation informed consent is implied; and (3) if alternative operative solutions exist and there are no immediate emergencies, the patient must be informed of the alternative possibilities and be given a chance to decide before the doctor proceeds with the operation.

Materiality. Determining the material risks inherent in a particular treatment or anesthetic is not clear cut. As a consequence of consumerism and increased emphasis on patient self-determination there is more ambiguity concerning what constitutes a material risk. Unfortunately, what may seem reasonable or material to one patient may not be to another. The majority of states use the medical standard, others rely on the lay standard, while still others (e.g., Maryland) use both standards (Aiken & Catalano, 1994). With neither standard emerging as the dominant legal principle, the extent of disclosure is unclear. "Materiality is . . . the product of risk and its chance of occurring" (Gild, 1989, p. 653). Presumably, this attaches significance to the risk in deciding whether or not to

consent to the proposed treatment. Under the lay standard the patient must prove that disclosure of the risk would have caused an average, reasonable patient to forgo the treatment (Cobbs v. Grant, 1972). Thus, the non-disclosure of the risk caused the injury that resulted when the risk materialized. Fortunately, all risks are not equal. Instead, the practitioner's training and experience can serve as a guide in determining what risks the average, reasonable patient would want to be informed (Gild, 1989). Epstein & Blumenreich (1987) sum up risk materiality best by stating,

There are no absolute standards regarding what statistical percentage of risk is material and requires disclosure; there are cases which have found a violation of the informed consent doctrine when the patient was not adequately informed of adverse consequences which carried less than 1% likelihood of risk or complication. (p. 507)

It is important to understand how materiality can be applied to clinical anesthesia. Anesthesia providers need not apprise patients of remote risks. For example, in Lindquist v. Ayerst Laboratories (1980), the patient had undergone two surgeries within a sixteen day period and had received halothane as the general anesthetic for both. Four days following the second surgery, the patient became icteric, lapsed into a coma, and eventually died of liver failure. The patient's estate claimed that the second anesthesiologist neglected to inform the patient that potential liver damage could result from a second administration of halothane so soon after the first administration. The package insert for halothane warned against multiple administrations when the patient suffered from jaundice or an unexplained high fever. Although the patient had a fever, it

was not a result of the halothane, but was from a staph infection. The court found that the anesthesiologist had properly informed the patient of the significant risks associated with halothane (Epstein & Blumenreich, 1987).

Similarly, courts have held that a healthy patient undergoing a relatively minor surgery need not have the risk of death disclosed because it is so remote, thereby making it immaterial. In contrast, in surgery on a patient who rates an American Society of Anesthesia (ASA) physical status 4 classification (a patient with an incapacitating systemic disease that is a constant threat to life) the risk of death should be mentioned by virtue of its gravity (Gild, 1989). The following figure (1) assists in determining whether or not the patient should be informed of risk materiality. The severity (high, low) of a potential injury and the risk (high, low) of an adverse result occurring are matched to determine materiality. For example, a cut lip during laryngoscopy is low in severity, but has a relatively high risk of occurring. Therefore, the figure indicates that the risk is material.

		Severity of Potential Injury	
		Low	High
Risk of an Adverse Effect	High	Yes	Yes
	Low	No	Discretion

Legend

Discretion - Patient should be informed at the discretion of the provider

Yes - Patient should be informed

No - Patient should not be informed

Figure 1. An algorithm for determining risk materiality.

As mentioned previously, actions based solely on informed consent rarely arise in medical malpractice litigation because of two reasons. First, most injuries result from negligence, not from lack of informed consent. Second, to prove failure to obtain informed consent, the patient has to prove not only that he would have forgone the anesthetic, but that the risk in fact did materialize. A charge of non-disclosure alone without injury is referred to as a dignitary tort. Dignitary torts have yet to be monetarily compensated (Gild, 1989).

Contract Law

Contract law is a third legal concept that may form the basis of a lawsuit founded on a lack of informed consent. As mentioned previously, the modern principle of informed consent rests on a negligence theory. Negligence, in turn, falls under tort law. It is important for the anesthesia provider to understand that contract law also comes into play in informed consent cases. The provider is entering into a contract to provide professional services. Consequently, the provider needs to become familiar with basic contract principles that come into play during the informed consent process (McDonough et al., 1995).

A contract is defined in its broadest sense as “a promise or set of promises for breach of which the law gives a remedy, or the performance of the law in some way recognizes as a duty” (Lord, 1990, p. 2). The four relevant factors in a contractual relationship are the offer, acceptance, consideration, and breach. During the preanesthesia interview, the anesthesia practitioner (offeror) offers to provide anesthesia care to the patient (offeree). The patient has the “power of acceptance.” Consideration is defined as the economic cost of an agreement. In anesthesia situations the practitioner agrees to provide reasonable anesthesia care in exchange for payment for those services by the patient or the patient’s insurer. The payment is the consideration for the anesthesia services (Aiken & Catalano, 1994). If the patient accepts the practitioner’s offer and there is adequate consideration, a contract is created (Aiken & Catalano, 1994). The contract is a mutual manifestation of assent - termed “mutual assent” - to the same terms (Calamari & Perillo, 1977). The primary remedy for breach of contract is monetary damages. Usually, the goal of the courts is to place the injured party in the same economic position in which he would have been had the promise been kept (Aiken & Catalano, 1994).

Although the right to contract in the United States is protected by the Constitution, the principle of self-determination (sovereignty over one’s body) takes precedence in issues of informed consent (McDonough et al., 1995). Because there is a great disparity in knowledge between anesthesia providers and patients, the law protects the interests of the patient. For instance, the average, reasonable patient should not be expected to know the side effects, risks, or alternative anesthesia modalities of various

forms of anesthesia. McDonough et al. (1995) thought that patients should not be expected to make informed choices without complete and full disclosure by the provider.

Figure 2, below, is a summary of the differences between tort and contract law.

Law	Degree of Informed Consent	Case
Tort	Total Lack of Informed Consent	Negligence/Malpractice; Battery
Contract	Inadequate Informed Consent	Breach of Contract

Figure 2. A summary of the differences between tort and contract law.

Res ipsa loquitur

A fourth legal concept may also form the basis of a lawsuit founded on lack of informed consent. This is the principle of *res ipsa loquitur*, which shifts the burden of proof onto the defendant (Danzon, 1985). *Res ipsa loquitur* is a principle that translates into “the thing speaks for itself.” To take advantage of this doctrine, the plaintiff must be able to prove three criteria: “(1) The injury occurred under circumstances such that in the ordinary course of events the injury would not have occurred if someone had not been negligent, (2) the injury must be caused by something in the exclusive control of the defendant, (3) the injury must not have been due to any voluntary action or contribution on the part of the plaintiff” (Blumenreich, 1997, p. 33). Under this principle it is not necessary to show specific evidence of negligence. Therefore, the plaintiff’s lawyers do not have to obtain testimony as to the standard of care or obtain and present evidence that the standard of care was breached.

An example of *res ipsa loquitur* is presented in the case of Nielson v. Pioneer Valley Hospital (1992). The plaintiff argued that while under general anesthesia she had sustained several broken teeth and damaged bridgework during surgery. It is important to point out that the patient was unconscious from anesthesia and did not know who caused the damage or how it occurred. The plaintiff pursued two means of recovery, negligence and *res ipsa loquitur*. The court instructed the jury that to find negligence on the part of the anesthesiologist, evidence other than adverse results had to be found. Although this may be true in negligence, it is not true in *res ipsa loquitur*. Under the theory of *res ipsa loquitur*, the adverse result “speaks for itself.” Even though the jury rendered a verdict in favor of the anesthesiologist, the Utah Supreme Court reversed the case and ordered a new trial because the original instructions were confusing (Blumenreich, 1997).

In a similar case, Chism v. Campbell (1996), the defendant (anesthesiologist) submitted affidavits that stated there always exists an inherent risk of tooth damage from the patient biting down on the endotracheal tube during emergence from anesthesia without negligence by the anesthesiologist. If this is true, then *res ipsa loquitur* would not apply because the damage may occur without provider negligence. Preventing *res ipsa loquitur* from being used against the anesthesia provider in the courtroom starts with disclosing to the patient, during the informed consent process, such risks as dental damage (Blumenreich, 1997).

Proper informed consent during the preanesthesia interview not only ensures shared decision making between the provider and the patient, but also helps to prevent lawsuits under the legal theories of negligence, battery, breach of contract, and *Res ipsa*

loquitur. Materiality also plays an important part in the informed consent process. The degree of severity and risk should help guide the provider whether to disclose potential injury to the patient.

CHAPTER 3: CONCEPTUAL FRAMEWORK

Both advanced practice registered nurses and physicians are obligated, by virtue of their standards of practice, to integrate ethical principles into their practice (American Nurses Association, 1996; Maynard et al., 1992). Adequate disclosure is one of these ethical principles. “The advanced practice registered nurse informs the client of the risks, benefits, and outcomes of health care regimens”, (American Nurses’s Association, 1996, p. 19). Likewise, physicians are required to provide enough information to allow a patient to make an informed judgment about how to proceed or not to proceed with various treatment modalities. Maynard and colleagues (1992) state, “The physician is obligated to ensure that the patient or, where appropriate, the surrogate be adequately informed about the nature of the patient’s medical condition, the objectives of proposed treatment, treatment alternatives, possible outcomes, and the risks involved” (p. 949). This chapter will describe those ethical concepts which formed the underlying ethical framework for this research.

Siegler and co-investigators (1991) contend that the process of informed consent should be grounded on the theory of clinical ethics. The purpose of clinical ethics is to improve the quality of patient care by analyzing and attempting to resolve ethical dilemmas that impact clinical practice. Because this study examines performance disclosure of the elements of informed consent in the preanesthesia interview, an ethical dilemma that effects quality of patient care, an ethical framework will be used.

Philosophically, the informed consent doctrine emphasizes equalization of the practitioner/patient relationship and decision-making rights. The basis of modern informed consent is a triad of the ethical concepts of autonomy, beneficence, and justice (Gild, 1989).

Autonomy

Autonomy refers to self-governance through adequate understanding (Gild, 1989). Providers have the duty to protect and foster an individual's free and uncoerced choices (Maynard et al., 1992). It embraces the right to receive information and to act on it by giving or withholding consent. If the provider merely allows the patient the final say in deciding a treatment alternative, without first providing any relevant medical information, then the informed part of the informed consent is absent (Gild, 1989). Patients must be informed of the five elements of informed consent. Additionally, if the practitioner provides all of the information but denies the patient the right to make a decision, then the consent part of informed consent is not fulfilled.

Beneficence

The primary responsibility of the health care provider is to safeguard the welfare of the patient. Historically, this responsibility was expressed by the Latin expression of *primum non nocere* which means in the first place, do no harm (Gild, 1989). However, a more precise translation is help, or at least do no harm. This change in translation obligates the practitioner to provide a benefit to patients, not merely to avoid harm. Medical professionals can provide benefit to patients within the decision-making process

by providing the patient with sufficient information with which to arrive at an informed decision and allowing the patient to make decisions relating to his or her own care.

The concept of beneficence mandates that the patient have the opportunity to make decisions, thereby embracing the process of informed consent (Gild, 1989). In some instances there may be a conflict between patient choices and provider choices as to appropriate treatment. Sulmasy, FitzGerald, and Jaffin (1993) note that patient good incorporates not only biomedical health, but also the patient's interests and basic human dignity. For example, amputation of a gangrenous leg may be efficacious in treating an infection; however, the patient may not consider life with only one leg beneficial.

Justice

The last principle of the ethical triad of informed consent is the concept of justice. Justice is achieved when people are treated equally under similar circumstances (Gild, 1989). The principle of distributive justice requires that we seek the morally correct distribution of benefits and burdens in society. Under a system of justice, anesthesia providers are obligated to give all patients in similar circumstances the same pre-operative information. If a provider omits portions of the preoperative discussion due to patient race, education level, or other such factors, the provider would not be providing just patient care. Furthermore, providers often determine distribution when allocating resources to patients (Maynard et al., 1992). For example, in some situations, military retirees may receive lower priority for elective surgery than their active-duty

counterparts. It is in scenarios such as these that concerns about justice challenge the role of providers as patient advocates.

Providing autonomy, beneficence, and justice to patients during the informed consent process helps ensure that patients can make autonomous anesthetic choices. Philosophically, informed consent doctrine emphasizes equalization of the physician/patient relationship and decision-making rights (Gild, 1989). “Ethically valid consent is a process of shared decision-making based on mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments” (President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982, p. 2). This study examines the level of disclosure of the informed consent elements during the anesthesia interview. It is through this ethical conceptual framework that a complete disclosure to the patient is based.

CHAPTER 4: METHODOLOGY

This chapter outlines the methods used to implement this descriptive quantitative study. The sections within this chapter will include the research instrument, sample selection, and data collection method.

Instrument

Content. The data collection instrument used in this study was developed after a thorough review of the literature revealed few instruments which have addressed informed consent in the preanesthesia interview. Rosoff (1979) developed a questionnaire in which internists and surgeons rated themselves on informed consent disclosure performance utilizing the five elements of informed consent. The survey used in this study contains 21 questions developed from a larger pool of questions from the Rosoff study (Appendix A). The study questionnaire was adapted so that patients could rate anesthesia providers on informed consent disclosure performance in the preanesthesia interview.

To ensure participant readability, all questions were written with the assistance of two instrument design experts, exclusive of the committee members. The instrument also included demographic questions (gender, age, ethnicity, marital status, educational status), interviewer identification (nurse anesthetist, anesthesiologist, etc.), length of instruction, and comprehension of data disclosed (self-assessed).

Validity. To ensure face validity, all questionnaire items were evaluated by the thesis committee members prior to the proposal defense. Content validity was also

evaluated by three experts who reviewed and approved the survey instrument before the proposal defense. The evaluators included one nurse-attorney, an attorney, and an anesthesiologist.

Reliability. The reliability of the survey tool was measured by using a test/retest method. The pilot study was conducted over a four day period. Eight of 20 subjects completed the retest portion for a 40% retest response rate. Each individual participating in the pilot study received two copies of the survey. The first copy of the survey was completed directly after the preanesthesia interview. The second survey was distributed in a sealed envelope with instructions to complete one week or the day before surgery, whichever came first. The patient then placed the survey in the stamped, addressed envelope provided and mailed it to the investigator. The pilot surveys were coded to match the first survey with the second. The results of the two questionnaires were compared to determine how the concept of informed consent stood over time.

Sample Selection

A convenience sample was drawn from the population of active duty, retirees, and dependents who were surgical/anesthesia candidates at a medium sized Air Force Medical Treatment Facility. Sample size for this study was determined using the method developed by Kraemer and Thiemann (1987). Forty-five subjects were needed based upon a power of 80% for a 5% two-tailed test with a critical effect size of 0.40.

Data Collection Method

Following their preanesthesia interview, all subjects were approached by the investigator and asked to participate in the study. First, the potential subjects were given a verbal description of the study (Appendix B). Those who consented to participate in the study were given the study questionnaire. The subjects were instructed to return the completed questionnaire to the investigator while on site.

Ethical Considerations

Participation in this study was voluntary. A verbal script was included with the survey to explain the purpose of the study (Appendix B). Anonymity and confidentiality were assured. Survey forms were not coded in any way that could identify the respondent by name.

Respondents were instructed not to write their names on the survey form. Participants in the pilot study had numbered surveys to enable the matching of the original survey with the second survey. Completed surveys were placed in sealed box and only the investigator was allowed to access them. Completion of the survey was construed as implied consent. The participants were offered the opportunity to obtain the results of the study by contacting the Department of Anesthesiology. All study results were presented in aggregate form to further ensure confidentiality.

Approval for this study was granted from the institutional review boards at the command at which the study was conducted and the Uniformed Services University of the Health Sciences (USUHS).

Data Analysis

SPSS, a statistical computer software program, was used for a descriptive analysis that consisted of frequencies and percentages for each variable that elicited nominal data (questions 1-9). Variables at the interval level of measurement were analyzed by determining the frequency, percentage, mean, range, and standard deviation where appropriate (questions 10-21). Comparisons were made among gender, age, ethnicity, military status, education, type of interviewer, interview length, and levels of understanding regarding content of interview with respect to disclosure performance of the informed consent elements in the preanesthetic interview.

CHAPTER 5: DATA ANALYSIS

This chapter presents a description of the data obtained from the questionnaires completed by 53 subjects after the preanesthesia interview. The questionnaire addressed demography, type of provider conducting the interview, length of instruction, and patient perception of disclosure performance of the informed consent elements.

Pilot Study

Sample Description

Twenty surveys were initially completed over a 4-day period. Of the 20 surveys, eight subjects responded by filling out an identical second survey (40% response rate) for the test/retest methodology. The following results were calculated from the retest data. One respondent answered only 6 of the 21 questions on the survey. This subject answered most of the demographic questions, and the data is incorporated into those results.

The majority of the respondents were Caucasians. There was one outlier who responded to the ethnicity question by reporting to be an “American” under the response of “other” on the survey. Most of the subjects were single (n=4) or divorced (n=2). An equal number of males (n=4) and females (n=4) responded in this study. The age range of the subjects was 22 to 79 years of age, with a mean of 48 years (SD = 20.2). Of the military respondents three were enlisted, three were retirees, one was a chief warrant officer, and one, a civilian dependent. Six of eight respondents reported having a high

school diploma, and two subjects reported having graduate degrees (one master's, one doctorate).

Alpha reliability coefficients were calculated on all test and retest study subjects. Alpha scores varied from 0.76 to 1.00. Subjects were consistent in response from the administration of first survey to the second.

Provider Type, Length of Instruction, and Level of Understanding

Three subjects reported that they were interviewed by physicians. One subject stated that the interview was conducted by an anesthesiology resident, although there were no anesthesiology residents at this medical treatment facility. It was this type of confusion regarding the type of provider who conducted the interview that necessitated the investigator to determine who was the actual provider. Nurse anesthetists were reported to be the interviewer in three cases. One respondent reported that the provider did not identify him/herself, while another respondent did not answer the question.

Four subjects stated that the interview lasted 15 minutes. The two remaining subjects reported 10 and 20 minutes respectively. There was missing data on two of the surveys regarding this question. Six of eight respondents reported that they understood most or all that was discussed. The remaining two respondents reported that they understood the basics of what was discussed, but not the details.

Primary Study

Sample Description

A convenience sample of 53 surveys were completed over a period of 36 days in the same military facility as the pilot study. The number of male respondents approximated the number of female respondents, 26 and 27 respectively. The age range of the patients was 19 to 76 years, with a mean age of 44 years. Sixty percent of respondents were Caucasians, 32% of respondents were African American. In contrast to the pilot study, nearly 72% of respondents were married, and approximately 15% of respondents were single.

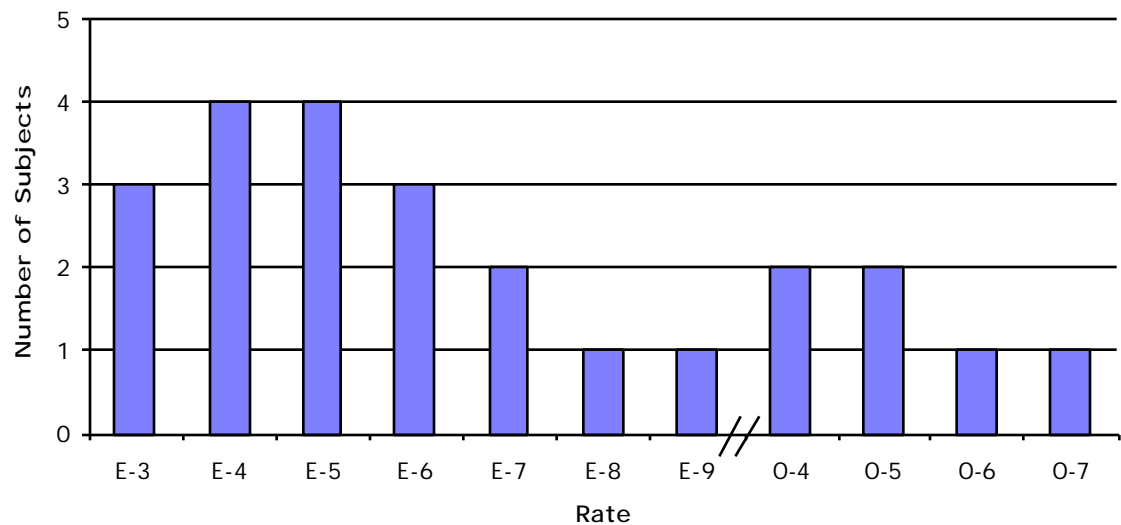


Figure 3. Military status of patients by rate.

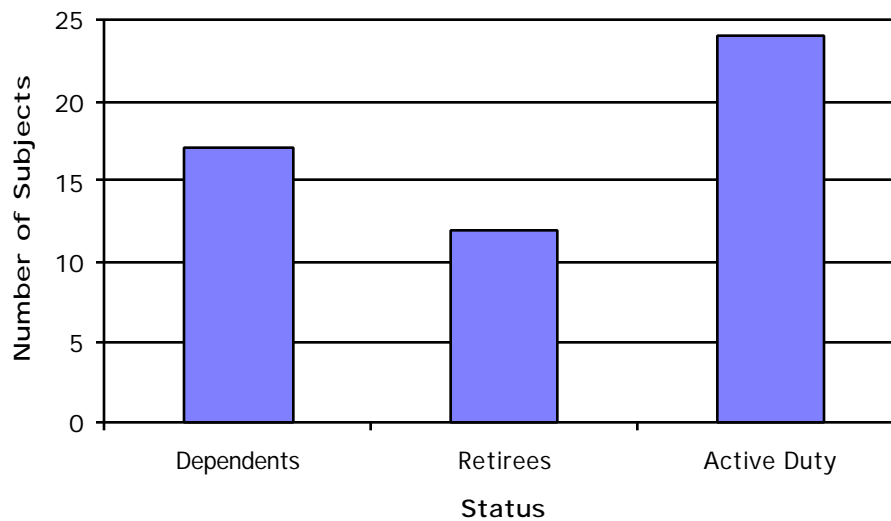


Figure 4. Military status of patients.

The military status ratios of the subjects in this study closely resembled expectations; nearly 55% were dependents and retirees. Dependents and retirees require medical care at a higher rate than the younger active duty officers and enlisted personnel. Approximately 70% of Department of Defense (DoD) hospital admissions worldwide were for dependents and retirees (DoDa, 1997). Enlisted personnel in this study outnumbered officers at a rate of three to one. This sample of officers is proportionally about twice the size of today's military (DoDb, 1997).

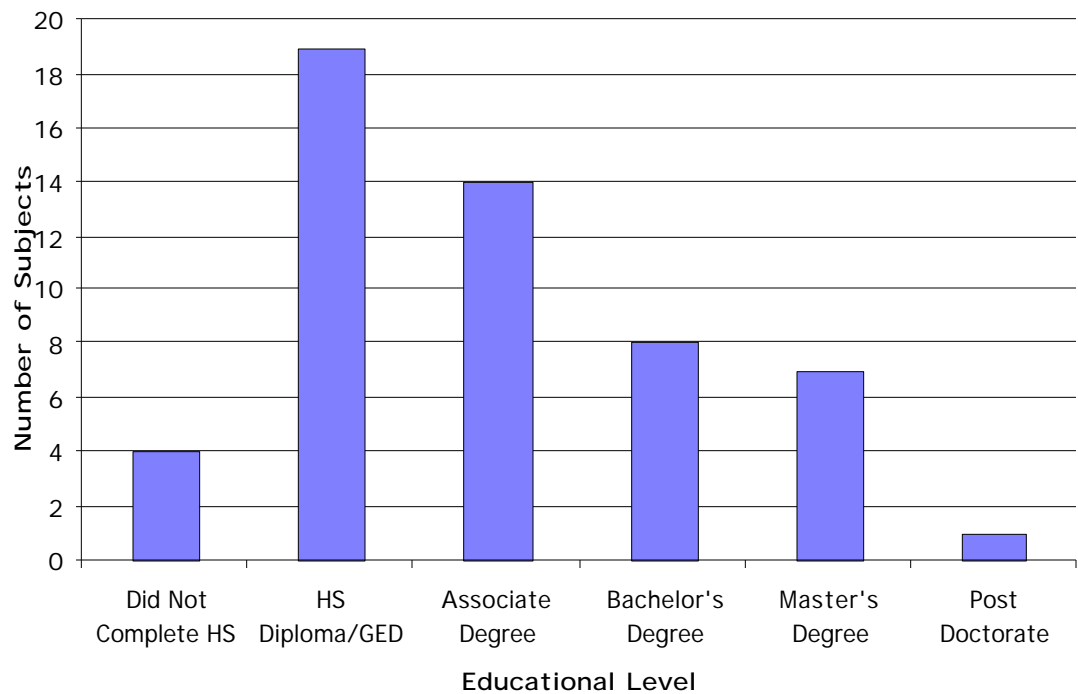


Figure 5. Highest educational level attained.

Thirty percent of the subjects had a bachelor's degree or higher. Most had an associate's degree or a high school diploma/GED. The sample is on average more educated than the United States population and the military as a whole (U.S. Bureau of the Census, 1995, p. 160; Office of the Assistant Secretary of Defense, 1996, p. 3-11, 4-16). Other than warrant officers, a bachelor's degree is the entry level educational requirement to become an officer. Most enlisted personnel have a high school diploma/GED or an associate's degree.

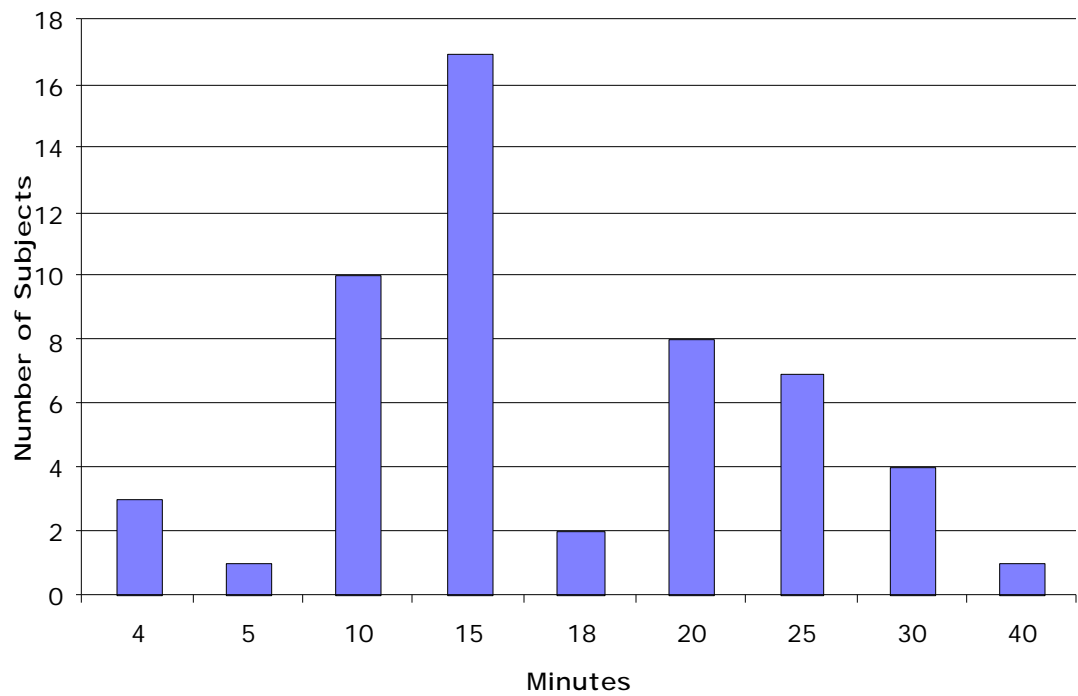


Figure 6. Length of preanesthesia interview in minutes.

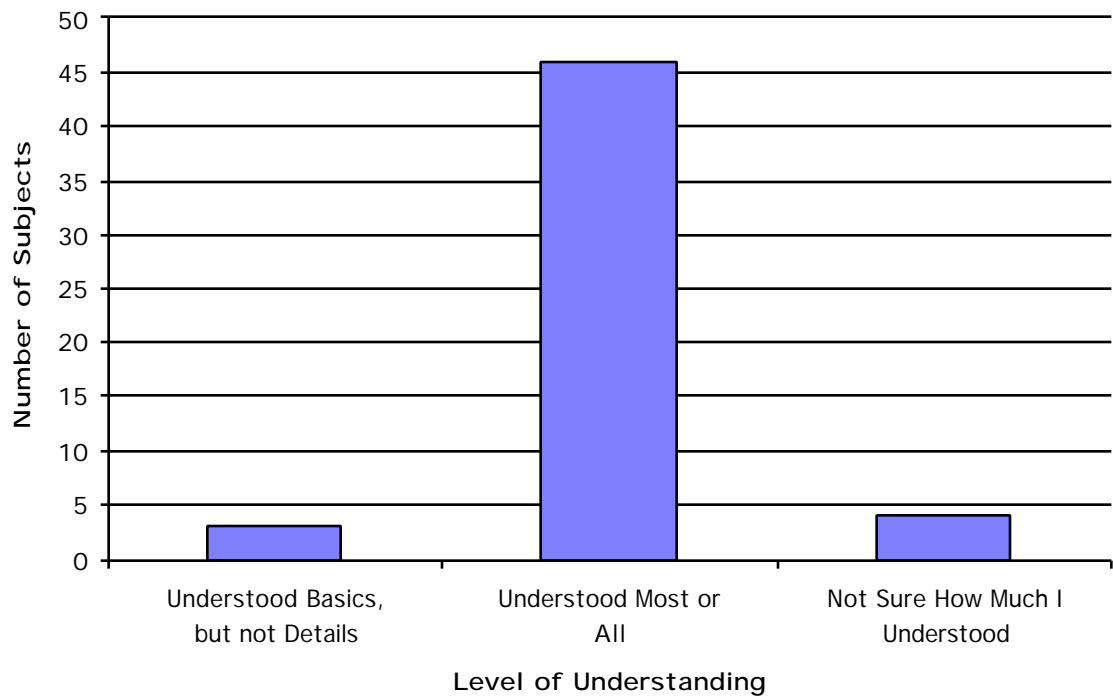


Figure 7. Level of understanding of preoperative information by sample size.

Most of the preanesthesia interviews lasted between 10 and 20 minutes. Figure 5 illustrates the distribution of responses. Eighty-seven percent of all respondents reported that they understood most or all of what was discussed during the preanesthesia interview. Figure 6 depicts the level of understanding reported by the respondents. There was no correlation between the subject's reported level of understanding and educational level and length of the preanesthesia interview.

The Four Elements of Informed Consent

The last 11 questions on the survey pertained to the four elements of informed consent. The questions were written using a 5-point Likert scale format, with 1 not discussed at all to 5 very thoroughly discussed. Each point on the Likert scale was assigned a description for ease of understanding. The subjects were asked to circle their opinion as to the extent of disclosure regarding the four elements of informed consent.

Nature of the proposed anesthesia. More than 90% of the subjects (n=49) reported that the expectations of a particular anesthetic and the type of anesthetic to be received was discussed more than average or in detail.

Benefits of the proposed anesthesia. The overwhelming majority of respondents, 81% (n=43), reported that the benefits of the anesthesia recommended to them by the provider were discussed more than average or in detail. The percentage decreased slightly when the topic of success was discussed. Approximately 74% of respondents rated the disclosure as more than average or in detail. When the benefits and success rate of alternative forms of anesthesia were discussed, nearly one quarter of respondents

reported that neither was discussed. However, about 60% of the subjects still noted that the providers discussed more than average or in detail the aforementioned topics during the interview.

Risks of the proposed anesthesia. Similar trends already discussed for the disclosure of the benefits also are found with the disclosure of risks. More than 90% of subjects reported that the risks and side effects associated with anesthesia were discussed either more than average or in detail. Nearly 20% thought that the disclosure of the risks associated with alternative types of anesthesia was not discussed at all. Conversely, about 70% of respondents reported that the aforementioned topic was discussed more than average or in detail.

Alternative anesthetic modalities. As expected from previous discussions on benefits and risks, approximately 30% of the subjects reported that alternative forms of anesthesia was discussed not at all, very little, or somewhat. Nearly 70% still reported that the topic was discussed more than average or in detail. Even more significant, when the topic changed to the pros and cons of alternative anesthesia versus the primary anesthesia, nearly 40% (n=21) of respondents reported that disclosure was not at all, very little, or somewhat. Sixty percent (n=32) still reported that the topic was discussed either more than average or in detail.

Kendall's Tau Correlations among Demographic Data and Informed Consent Elements

In computing a Kendall's tau correlation, the total score for the questions relating to the four elements of informed consent was computed in the following manner. There

were five possible responses for each of the 11 questions. The highest possible score of 55 was only attainable by the respondent rating the extent of the disclosure a 5 for each question. Conversely, the lowest possible score of 0 was only attainable by the respondent not rating the extent of the disclosure for each question. The total score was then correlated with the data from demographic questions. Finally, all 53 individual responses were averaged for the final Kendall's tau correlation. This variable is defined as the total for the informed consent elements in the discussion section.

There was a moderately significant correlation, as defined by Munro and Page (1993), a 0.584 rating, among the variables of the total for the informed consent elements, pros and cons of alternative anesthesia versus primary anesthesia, and alternative forms of anesthesia. There was a low statistical inverse correlation of -0.217 between the total for the informed consent elements and highest educational level attained (Munro & Page, 1993). The inverse relationship suggested that the higher the educational level, the lower the total score on the critical four elements of informed consent. There were no significant correlations found among the following variables, the total for the informed consent elements and gender, age, ethnic group, marital status, military status, and length of preanesthesia interview.

Perceived versus Actual Provider Type

Using Kendall's tau, a low statistical correlation of 0.370 was found between those identified by the patient as the provider and the actual provider (Munro & Page, 1993). Subjects identified an anesthesiologist as the provider in 18 of the 53 interviews

conducted. However, only three interviews were conducted by anesthesiologists. Similar to the pilot study, anesthesiology residents were identified as the provider in five interviews, although there were no anesthesiology residents at this institution. Only six subjects responded that the provider either did not identify him/herself or the subject forgot who was the provider.

There are many possible explanations for this low statistical correlation. First, most nurse anesthetists at this command were male, and it is possible that many patients identify a male anesthesia provider as being a doctor instead of a nurse. Second, it was observed that many nurse anesthetists identify themselves by rank instead of provider type. Interestingly, it was also observed that physicians identified themselves as such in most of the interviews. Third, when the patient was identified as an ASA Classification 3 or higher, it is possible that the patient was also introduced to and interviewed by the anesthesiologist leading to confusion as to who the actual provider was. Even though the patient might have been seen by an anesthesiologist, it should be recognized that the nurse anesthetist spent more time with the patient as the primary interviewer. Fourth, the term resident has most often been associated with physicians during their post medical school training. Students from the Uniformed Services University of the Health Sciences Nurse Anesthesia Program are encouraged to introduce themselves as nurse anesthesia residents. This terminology could have led to patient confusion as to whether the practitioner was a nurse or a physician in training to become an anesthesia provider. Fifth, nurse anesthetists are not as widely known by the public as anesthesiologists. In the preface of Marianne Bankert's book (1993), Watchful Care: A History of America's Nurse

Anesthetists, one national news publication referred to nurse anesthetists as the best kept secret in medicine. Therefore, due to this lack of identity and similar sounding nomenclature, it is possible that the public may combine both provider types under the category of anesthesiologists.

CHAPTER 6: DISCUSSION

This chapter provides a summary of the study, recommendations and conclusions drawn from the data in chapter five. Areas of the study will be addressed in terms of the informed consent elements. For the purposes of this discussion, risks and benefits are grouped together. The chapter will conclude with the limitations and strengths of the study.

The Four Elements of Informed Consent

Nature of the proposed anesthesia. The first two questions on the survey dealt specifically with the nature of the proposed anesthesia. The questions sought to determine the level of provider disclosure regarding the expectations and type of particular anesthetic chosen. Overwhelmingly (over 90%), subjects perceived that these two questions were discussed more than average or in detail.

This high level of disclosure is not surprising. After the patient history and physical, providers often tell their patients what type of anesthetic is recommended. This information is pivotal since all other informed consent elements hinge on knowing the nature of the proposed anesthesia.

Patients want to know what they will likely experience. From the patients' perspective, this is perhaps the most important question. Many patients just want to be assured that they will be unconscious (given a general anesthetic) for a particular procedure so that they will not experience any pain. Many patients will ask the provider for this information themselves if it is not discussed in a timely manner.

Benefits and risks of the proposed anesthesia. The benefits and success of the proposed anesthesia were discussed by the providers more than average (81%) or in detail (74%) of the time. Likewise, risks and side effects were discussed 90% of the time. However, one quarter of the respondents reported that neither benefits nor success of the alternative forms of anesthesia were discussed. Similarly, one fifth of the subjects noted that risks associated with alternative forms were not discussed. Sixty percent and 70% of the subjects thought that benefits and risks respectively were disclosed more than average or in detail.

Once the nature of the proposed anesthesia is given to the patient, it is then logical for the provider to proceed by disclosing the benefits and the risks of that procedure. Most providers are aware, under the medical standard, that risks and benefits are to be disclosed to the patient. The rates of disclosure for the nature, benefits, and risks of the proposed procedure in this study are similar. However, the disclosure rates of benefits and risks of the alternative forms of anesthesia are remarkably less.

Alternative anesthetic modalities. Nearly 30% of subjects reported that the alternative forms of anesthesia were either not or only somewhat discussed. Moreover, 40% of respondents reported that the pros and cons of the alternative anesthesia versus

the primary anesthesia was also disclosed in the same detail. Still, 60% of respondents reported that both subjects were discussed more than average or in detail.

Again, any information regarding alternative forms of anesthesia was disclosed at a far lower rate than the other three elements of informed consent. As a consequence, 20% to 40% percent of the time the provider would not be in compliance with the lay standard requirements. There are multiple reasons for this. One may hypothesize that the anesthetic procedure recommendations may be based on what procedure the provider would want if he or she underwent a similar surgical procedure, provider learning needs, cost of anesthetic procedure, provider's skill level, provider's lack of knowledge, and/or lack of time in conducting a thorough interview. Additionally, the anesthesia consent form (Appendix E) used at the medical treatment facility in this study focuses primarily on the anesthetic procedure to be performed with the corresponding material risks. If providers use this consent form as a guide, there is nothing to trigger a discussion on alternative forms of anesthesia.

Kendall's Tau Correlations among Demographic Data and Informed Consent Elements

Of all the correlations analyzed between the demographic data and the total for the informed consent elements, there was only one correlation of significance. There is a low inverse correlation of -0.217 between the total for the informed consent elements and the highest educational level attained. This suggests that the higher the educational level, the lower the total score on the critical four elements of informed consent. One explanation for this is that higher education fosters critical thinking skills, thereby enabling subjects

with a baccalaureate degree or higher to differentiate what elements were discussed and to what degree.

Limitations of the Study

The intent of this investigator was to have approximately the same number of nurse anesthetists as anesthesiologists conducting the preanesthesia interviews so that research question number 3 could be satisfactorily analyzed. Despite frequent requests made by this investigator to the Anesthesia Department Head via intermediaries, a mere three interviews were conducted by anesthesiologists. Nearly 91% of the interviews were conducted by nurse anesthetists. Two interviews were conducted by student nurse anesthetists. One possible explanation is that anesthesiologists were not consistently assigned to do pre-anesthesia interviews, despite encouragement from the Department Head. At this facility anesthesiologists are assigned to operating rooms. However, they are not usually providing direct anesthesia care except when relieving nurse anesthetists for breaks. Anesthesiologists are generally in a supervisory role at this institution. Interestingly, for any patient who is suspected of being an ASA Classification 3 or higher at the time of the preanesthesia interview, an anesthesiologist must be consulted. It may be more efficient to have anesthesiologists do more preanesthesia interviews, or at least the ASA Classification 3 or higher patients, so two providers do not see the same patient.

Other limitations of this study include the small sample size and the collection of data at one site, both of which limits the generalizability of the findings. The time span

between first and second completion of the survey in the pilot study was highly variable. This affects the reliability of the survey.

Strengths of the Study

There is a significant lack of information regarding level of disclosure of the four elements of informed consent in the preanesthesia interview. Adequate disclosure during the informed consent process ensures that the patient can make informed choices. Although there has only been one study (Rosoff, 1979) which surveyed physicians on their level of disclosure to patients, this is the first study to examine patients' level of perception regarding the disclosure of the informed consent elements.

Even though this study failed to recruit enough physicians to interview patients, the results can be considered significant in evaluating the proficiency of nurse anesthetists in disclosing the elements of informed consent in the preanesthesia interview. This study found that nurse anesthetists are very good at discussing the nature, risks, and benefits of the proposed surgery. The primary area for future improvement is discussing alternative modalities of anesthesia. This study also reinforces the conclusions of multiple other studies that patients do not know who are their providers.

Recommendations for Future Studies

The recommendations for further research include replicating this study with the following modifications: increasing the sample size, studying the civilian sector, and including physicians as a significant portion of the sample. Analysis of the impact of written and/or audiovisual materials in addition to the already existing preanesthesia

interview on the level of disclosure would also be of interest. Finally, a qualitative study may also assist in further describing strengths and weaknesses of preoperative anesthesia counseling.

Conclusions

This study has been beneficial in describing the extent to which patients report that the elements of informed consent are disclosed in the preanesthesia interview. Generally, nurse anesthetists do a good job in explaining the nature, benefits, and risks of the proposed surgery. However, patient explanations concerning alternative anesthetic modalities needs to be improved upon so that patients can make informed choices.

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APPENDICES

- A. Informed Consent Survey
- B. Verbal Script of Study Information
- C. Internal Review Board (IRB) Approval Letter (Andrews AFB)
- D. Internal Review Board (IRB) Approval Letter (USUHS)
- E. Institutional Anesthesia Consent Form

A. Informed Consent Survey

SURVEY INSTRUMENT REGARDING PATIENT PERCEPTION OF INFORMED CONSENT FOR ANESTHESIA

Please do not sign your name to the form.

Today's date is _____.

I. What is your gender? **(circle the correct number)**

1. Male
2. Female

II. Indicate your age on your last birthday. _____ years old

III. What is your race or ethnic group? **(circle the correct number or write in the blank provided if your ethnic group is not listed)**

- | | |
|---------------------|----------------|
| 1. Asian | 4. Caucasian |
| 2. Hispanic | 5. Other _____ |
| 3. African-American | |

IV. What is your marital status? **(circle the correct number)**

- | | |
|------------|-------------|
| 1. Single | 3. Divorced |
| 2. Married | 4. Widowed |

V. What is your current military status? **(please check the one appropriate blank)**

- | | | |
|-----------------|-------------------|----------------------|
| (1) E - 1 _____ | (11) O - 1 _____ | (21) Dependent _____ |
| (2) E - 2 _____ | (12) O - 2 _____ | (22) Retiree _____ |
| (3) E - 3 _____ | (13) O - 3 _____ | |
| (4) E - 4 _____ | (14) O - 4 _____ | |
| (5) E - 5 _____ | (15) O - 5 _____ | |
| (6) E - 6 _____ | (16) O - 6 _____ | |
| (7) E - 7 _____ | (17) O - 7 _____ | |
| (8) E - 8 _____ | (18) O - 8 _____ | |
| (9) E - 9 _____ | (19) O - 9 _____ | |
| | (20) O - 10 _____ | |

VI. What is your highest education completed? (**answer the most appropriate level by circling one number**)

- | | |
|---------------------------------|--------------------|
| 1. Did not complete high school | 5. Master's Degree |
| 2. High school diploma/GED | 6. Doctorate |
| 3. Associate's Degree | 7. Post Doctorate |
| 4. Bachelor's Degree | |

VII. Indicate who performed your preanesthesia interview before your surgery. (**circle the one correct answer**)

- | | |
|---|---|
| 1. Anesthesiologist (Doctor) | 5. The anesthesia provider did not identify him/herself |
| 2. Anesthesiology Resident | 6. I forgot/I do not know |
| 3. Nurse Anesthetist | |
| 4. Student Registered Nurse Anesthetist or Nurse Anesthetist Resident | |

VIII. Estimate how many minutes your preanesthesia interview lasted? _____ minutes

IX. Indicate how well you understood the information told to you by your anesthesia interviewer. (**circle only one number**)

1. I understood nothing which was discussed
2. I understood a little of the information discussed
3. I understood the "basics" of what was discussed, but not the details
4. I understood most or all of what was discussed
5. I am not sure how much I understood

Instructions: Below is a list of items which might possibly have been included as part of your preanesthesia interview. For each item, please circle the one number that best describes the extent to which the content was discussed with you by your anesthesia interviewer (1 = not discussed at all to 5 = very thoroughly discussed).

	Not discussed at all			Very thoroughly discussed	
X. What you can expect with the particular anesthetic that was chosen.	1	2	3	4	5
XI. What type of anesthesia you would be receiving (fully asleep or unconscious; local, spinal, or epidural anesthesia, etc.).	1	2	3	4	5

	Not discussed at all			Very thoroughly discussed	
XII. The risks generally associated with the type of anesthesia recommended.	1	2	3	4	5
XIII. The side effects from the particular type of anesthesia recommended.	1	2	3	4	5
XIV. The benefits which might be expected from the type of anesthesia recommended.	1	2	3	4	5
XV. The success of the anesthesia in surgical cases similar to yours.	1	2	3	4	5
XVI. Other types of anesthesia that might be used for your surgery in addition to the primary anesthesia type.	1	2	3	4	5
XVII. The risks and consequences of the <u>alternative</u> types of anesthesia that could be used.	1	2	3	4	5
XVIII. The benefits you might expect from the <u>alternative</u> types of anesthesia that could be used.	1	2	3	4	5
XIX. The probability of successful results from each of the <u>alternative</u> types of anesthesia that could be used.	1	2	3	4	5
XX. The pros and cons of the <u>alternative</u> types of anesthesia that might be used <u>versus</u> the primary type of anesthesia.	1	2	3	4	5

Thank you for participating in this survey.

B. Verbal Script of Study Information

After establishing eligibility for inclusion into the study, the researcher explained the purpose of the study and informed consent was obtained. The following script was related to the study participants:

“Hello, I am LT Brad Hartgerink, NC, USN. I am a nurse and graduate student in the Graduate School of Nursing at the Uniformed Services University of the Health Sciences. I am interested in looking at your perception of how well informed you are about the kind of anesthetic you will be receiving for your surgery. All adults over the age of 18 who are eligible to receive care here are being asked to participate. If you agree to participate, I will ask you to fill out a questionnaire. This should take approximately 15 minutes for you to complete. Your cooperation will help health team members better understand from a patient’s point of view whether the information received from your anesthesia provider was adequate in informing you about the kind of anesthesia you will be receiving.

Although this study will not directly benefit you, it might be of benefit to other patients in the future. All of the information that you give will be anonymous. If you decide not to participate in the study, this will in no way affect the care you receive at the time of your surgery. You will be free to withdraw from the study at any time by stating to me that you do not wish to participate in the study. This will in no way affect the care you are entitled to receive. You may ask me questions about the study.

After all of the research has been completed, a copy of the results will be available for you to review at the department of anesthesia.”

The researcher then gave the survey instrument to the subject.

C. Internal Review Board (IRB) Approval Letter (Andrews AFB)



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS 89TH AIRLIFT WING (AMC)



12 Jun 97

MEMORANDUM FOR LT BRADLEY J. HARTGERINK
10401 Grosvenor Pl., #706
Rockville, Md 20852

FROM: 89 MDG/SGI
1050 W. PERIMETER RD.
ANDREWS AFB, MD 20762-6600

SUBJ: Approval of Protocol: "Patient Perception of Disclosure Performance of Informed Consent Elements in the Preanesthesia Interview"

1. At the 11 June 1997 meeting, the Institutional Review Board (IRB) approved the subject protocol. You may begin your study.
2. Ensure all required reports are forwarded to this office promptly.


KIMBERLY P. MAY, Maj, USAF, MC
Chairperson

D. Internal Review Board (IRB) Approval Letter (USUHS)



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799



May 5, 1997

MEMORANDUM FOR BRADLEY J. HARTGERINK, DEPARTMENT OF
GRADUATE SCHOOL OF NURSING

SUBJECT: IRB Approval of Protocol T06131-01 for Human Subject Use

Your research protocol entitled "*Patient Perception of Disclosure Performance of Informed Consent Elements in the Preanesthesia Interview*," was reviewed and approved for execution on 4/17/97 as an **exempt** human subject use study under the provisions of 32 CFR 219.101(b)(4). This is a survey to obtain nonsensitive information in which there will be no identifiers linking the responses of the target group to the respondents.

Please notify this office of any amendments you wish to propose and of any untoward incidents which may occur in the conduct of this project. If you have any questions regarding human volunteers, please call me at 301-295-3303.

Michael J. McCreery, Ph.D.
LTC, MS, USA
Director, Research Programs and
Executive Secretary, IRB

Cc:
Chairperson, IRB
Director, Grants Administration
Vice President for Research

E. Institutional Anesthesia Consent Form

509-113 MEDICAL RECORD	NSN 75-90-03-634-4122 PROGRESS NOTES		
DATE:	ANESTHESIA INFORMED CONSENT		
<p> I understand that anesthesia involves risks and hazards but I request the use of anesthesia for relief and protection from pain during the planned procedure. I realize that the anesthetic may have to be changed possibly without explanation to me. I understand that certain complications may result from the use of any anesthetic including, but not limited to, respiratory problems, drug reactions, paralysis, brain damage or even death. Some other risks and hazards which may result from the use of general anesthetics range from minor discomfort to injury to vocal cords, teeth or eyes. I understand that other risks and hazards resulting from spinal or epidural anesthetics include headache and/or chronic pain. I HAVE BEEN GIVEN AN OPPORTUNITY TO ASK QUESTIONS ABOUT my condition, the types of anesthesia available and the risks, hazards and benefits of each. I believe that I have sufficient information and I give my consent for the use of _____ anesthesia, or any other type of anesthesia which may be required based upon a change in circumstances. I certify that this form has been fully explained to me and that I understand its content. </p>			
PATIENT/LEGAL GUARDIAN'S SIGNATURE: _____			
DATE: _____	TIME: _____ <small>(Continue on reverse side)</small>		
ANESTHESIA STAFF SIGNATURE: _____	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">REGISTER NO.</td> <td style="width: 50%;">WARD NO.</td> </tr> </table>	REGISTER NO.	WARD NO.
REGISTER NO.	WARD NO.		

 PROGRESS NOTES
 Medical Record

 STANDARD FORM 100-REV. 7-69
 Prescribed by GSA GEN. REG. 41 CFR 101-11.6-210-0

APPROVED HEALTH RECORDS COMMITTEE 19NOV87

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